



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/340,196	06/28/1999	RYOJI KATO	990701	3596
23850	7590	12/01/2006	EXAMINER	
ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP			HOLLERAN, ANNE L	
1725 K STREET, NW			ART UNIT	
SUITE 1000			PAPER NUMBER	
WASHINGTON, DC 20006			1643	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/340,196

**Applicant(s)**

KATO ET AL.

**Examiner**

Anne L. Holleran

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 59, 68-75, 77 and 78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59, 68-75, 77 and 78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The amendment filed 9/5/2005 is acknowledged. Claims 59, 68-75, 77 and 78 are pending and examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Maintained:***

3. Claims 59, 68, 69, 74 and 77 remain rejected under 35 U.S.C. 103(a) as being unpatentable over either Nakamura (U.S. Patent 5,571,729; issued 11/5/1996) or Satomura (U.S. Patent 5,780,247; issued 7/14/1998; effective filing 1/5/1991) in view of either Yamamoto (of record), Tarutani (of record), or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only).
4. Claims 70, 71, 77 and 78 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh (U.S. Patent 5,591,589; issued 1/7/1997) in view of either Yamamoto (of record), Tarutani (of record), or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only).
5. Claim 73 and 77 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Canfield (WO/87/00289;) in view of Yamamoto (of record).

Art Unit: 1643

6. Claim 72, 75 and 77 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh (supra) in view of Canfield (WO/87/00289;) and further in view of Yamamoto (supra) for the reasons of record.

***Response to Arguments:***

7. Applicants' arguments have been carefully considered but fail to persuade. Applicants have amended the claimed methods so that the claims are now drawn specifically to distinguishing between a malignant thyroid tumor and a benign thyroid tumor. Applicants compare the data presented in the specification with the data presented by Tarutani. Applicants assert that the prior neither teaches nor suggests the claim inventions. The claims remain rejected over the cited prior art because although the data presented in the specification may clearly differentiate between malignant and benign thyroid tumors, the prior art also teaches that such differences can be observed by comparing lectin reactivity. As pointed out in earlier Office actions, Yamamoto clearly compares malignant thyroids to benign and to normal on at least on pages 138 and pages 142. Yamamoto teaches that thyroglobulin isolated from malignant thyroid tumor tissue has a different DEAE-cellulose ion exchange elution pattern from thyroglobulin isolated from benign and from normal thyroids (page 138, first -2<sup>nd</sup> col.). Yamamoto teaches that the carbohydrate chains of thyroglobulin derived from the benign tumor had the same structures as those thyroglobulin derived from normal thyroid. Yamamoto teaches that thyroglobulin derived from malignant thyroid tumor contains less sialic acid, contains less high-mannose type carbohydrate moieties, contains oligosaccharides of high molecular mass with repeating Gal-GlcNAc disaccharides and peripheral alpha-fucosyl residues than does

Art Unit: 1643

thyroglobulin isolated from normal and benign thyroid tissue (page 142, 2<sup>nd</sup> col – page 143, 1<sup>st</sup> col). Yamamoto also teaches that using the lectin, ConA, one can differentiate between thyroglobulin isolated from malignant thyroid from thyroglobulin isolated from normal and benign thyroid. ConA affinity chromatography demonstrates that thyroglobulin from malignant thyroids contains more triantenary complex-type oligosaccharides than thyroglobulin from normal thyroids; RCA affinity chromatography demonstrates that thyroglobulin from malignant thyroids has a greater amount of asialo complex-type carbohydrate chains than does thyroglobulin from normal thyroids.

As stated in the previous Office action, Tarutani teaches that the percent of total thyroglobulin that binds to Con-A is different for trabecular carcinoma compared to either follicular adenoma (a benign condition) or normal thyroid tissue (see page 855, Table II). Therefore, Tarutani supplies the teaching that lectin reactivity is different for a malignant condition compared to a normal or a benign condition.

As stated in the previous Office action, Survillo compares malignant and benign tumors.

As stated in the previous rejection, Yamamoto teaches that thyroglobulin derived from malignant thyroid tumor contains less sialic acid than does the thyroglobulin of normal or benign thyroids, and that RCA-affinity chromatography demonstrates that thyroglobulin from malignant thyroids has a greater amount of asialo complex-type carbohydrate chains than does thyroglobulin from normal thyroids. Therefore, Canfield's teaching of a method to measure differentially glycosylated thyroglobulin and Yamamoto's teaching that thyroglobulin derived from malignant thyroid tumor contains less sialic acid than does the thyroglobulin of normal or

Art Unit: 1643

benign thyroids clearly suggests the claimed method, because Yamamoto teachings provide the nexus between differential glycosylation and malignancy of thyroids. Thus, the purpose of the claimed methods is suggested by the prior art.

Because each of Yamamoto, Tarutani or Survillo teaches that malignant may be compared to benign tumors and that a difference in lectin reactivity is seen between malignant and benign tumors, each of these references suggests the claimed methods with respect to detecting differences in lectin reactivity of thyroglobulin sugar chains. The specific method steps that refer to how to analyze ratios of glycoprotein lectin reactivity are provided by the teachings of Nakamura, Satomura or Katoh. Therefore, the rejections over the cited prior art is maintained for the reasons of record.

### ***Double Patenting***

8. Claims 59, 68, 69, and 74 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 5-9 of U.S. Patent No. 5,780,247 in view of either Yamamoto (of record), Tarutani (of record) or Survilo (Survilo, L.I. et al., Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk, 4: 103-107, 1997; abstract only). The claimed inventions are an obvious species of method that are within the scope of claims 1 and 5-9 of U.S. Patent No. 5,780,247. In view of the teachings of either Yamamoto, Tarutani or Survilo, that thyroglobulin is a glycosylated protein and that thyroglobulin derived from malignant thyroids contains a different glycosylation pattern, and in

Art Unit: 1643

view of the teachings that this can be observed by measuring differences in lectin-reactivity, the claimed inventions are an obvious species of the methods of claims 1 and 5-9 or U.S. Patent 5,780,247.

Applicants' remarks concerning the filing of terminal disclaimer when allowable subject matter is determined is acknowledged.

9. Claims 70, 71 and 78 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,591,589 in view of either Yamamoto (of record), Tarutani (of record) or Survilo (Survilo, L.I. et al., *Vestsi Akademii Navuk Belarusi, Seryya Khimichnykh Navuk*, 4: 103-107, 1997; abstract only). The claimed inventions are an obvious species of method that are within the scope of claims 1 and 3 of U.S. Patent No. 5,591,589. In view of the teachings of either Yamamoto, Tarutani or Survilo, that thyroglobulin is a glycosylated protein and that thyroglobulin derived from malignant thyroids contains a different glycosylation pattern, and in view of the teachings that this can be observed by measuring differences in lectin-reactivity, the claimed inventions are an obvious species of the methods of claims 1 and 3 or U.S. Patent 5,591,589.

Applicants' remarks concerning the filing of terminal disclaimer when allowable subject matter is determined is acknowledged.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1643

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished



Art Unit: 1643

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
November 27, 2006

A handwritten signature in black ink, appearing to read 'LRH', is positioned above the printed name and title of the signatory.

LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER